

REMARKS

Reconsideration of the outstanding objection and rejections and prompt allowance of this application are requested. Applicant notes with appreciation the withdrawal of the rejections under 35 U.S.C. §§ 102 and 103.

Claims 1-7 and 9-14 are pending in this application. These claims are in condition for allowance.

New claims 13 and 14 are directed to particularly preferred embodiments of the present invention. Support for these new claims may be found, for example, on page 3, lines 25-28, of the specification.

The Examiner has objected to the specification under 35 U.S.C. § 112, first paragraph, and has rejected claims 1-7 and 9-12 for the same reasons. More specifically, the Examiner has alleged that the scope of claim 1 "is too broad as it reads on and encompasses any amino acid or any one of its salts or any of its homologs or any detergent or any organic polymer or any permutation of combinations." Applicant respectfully traverses.

To be enabling under § 112, ¶ 1, the specification must teach the skilled artisan how to make and use the claimed invention without undue experimentation. Raytheon Co. v. Roper Corp., 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984). That some experimentation is necessary does not preclude enablement, unless the amount of experimentation is unduly extensive. Utter v. Hiraga, 845 F.2d 993, 998, 6 U.S.P.Q.2d 1709, 1714

(Fed. Cir. 1988). Nothing more than objective enablement of the invention is required. In re Marzocchi, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971).

The present invention, as defined in claim 1, is directed to a stabilized solution with factor VIII:C activity containing an amino acid or one of its salts or homologs and a detergent or an organic polymer, wherein the specific factor VIII:C activity is at least 1000 IU/mg. Applicant's specification teaches one of ordinary skill how to combine an amino acid with a detergent or an organic polymer to achieve a stabilized solution with factor VIII:C activity of at least 1000 IU/mg. Specification, p. 2, line 33 to p. 3, line 5; p. 3, lines 25-34; and pp. 5-7, Examples 1 and 2. No undue experimentation is required. *0*(<sup>c</sup>)

The present specification fully describes and enables the practice of the claimed invention. More particularly, in the specification, applicant (1) describes amino acids, detergents and organic polymers, (2) discloses a simple test to determine if a particular solution is stabilized, and (3) provides examples demonstrating stabilized solutions with various amino acids, detergents and organic polymers. Specification, pp. 2-4; see also Specification, pp. 5-7, Examples 1 and 2.

There is no mystery about the scope of the term "amino acids". As shown in the attached page from *Hawley's Condensed Chemical Dictionary*, amino acids are very well-known in the chemical arts. Similarly, "salts" and

"homologs" of amino acids are well-known in the chemical arts. See Hawley's Condensed Chemical Dictionary (attached).

Nor is there any mystery about the scope of the terms "detergents" and "organic polymers", the other component(s) of the stabilized solution. Again, as shown in the attached pages from *Hawley's Condensed Chemical Dictionary*, detergents and organic polymers are very well-known in the chemical arts.

Moreover, as indicated by the Federal Circuit in Raytheon and Utter, supra, the question is whether the present specification enables one of ordinary skill to practice the claimed invention without undue experimentation. When rejecting a claim for lack of enablement under § 112, ¶ 1, the PTO bears the initial burden of providing some reason why the scope of protection sought is not adequately enabled by the specification. In re Wright, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993).

The sole reason the Examiner provides to support this rejection under § 112, ¶ 1, is the statement that "[t]he scope of claim 1 is too broad" and concludes therefrom that "[i]t is an open invitation to experiment." The Examiner, however, has failed to cite a shred of evidence or reasoning to support this statement or conclusion.

Moreover, the Examiner is reminded that there is no fixed number of compounds which must be named or examples given to provide adequate support for a broad claim. See, e.g., In re Shokal, 242 F.2d 771, 113 U.S.P.Q. 283 (C.C.P.A.

1957). Simply because the present specification and claims employ generic terminology does not provide sufficient grounds to support the outstanding objection and rejection.

Some experimentation may, in fact, be necessary to make and use various stabilized solutions as claimed. The present specification, however, provides a facile and routine screening test to determine whether any particular solution is stabilized. Specification, pp. 5-7, Examples 1 and 2. Thus, if any experimentation is needed, that "experimentation" would be nothing more than the routine work for one of ordinary skill.

For these reasons, withdrawal of the outstanding objection and rejection under 35 U.S.C. § 112, first paragraph, is requested.

The Examiner has also rejected claims 1-7 and 9-12 under 35 U.S.C. § 112, second paragraph. As ground for this rejection, the Examiner has asserted that the terms "amino acid", "salt", "homolog", "detergent" and "organic polymer" are indefinite. Applicant respectfully traverses this rejection.

A broad claim, no matter how broad, is not indefinite for purposes of section 112, second paragraph, as long as the boundaries of the claim are capable of being understood by one skilled in the art. In other words, breadth alone is not indefiniteness. In re Gardner, 427 F.2d 786, 166 U.S.P.Q. 138, 140 (C.C.P.A. 1970).

Consequently, a broad claim employing well-known language conventionally used in the art of the invention, to define adequately the metes and bounds of the claimed invention, and which is of the same scope as the description of the invention contained in the disclosure, is not objectionable under the second paragraph of 35 U.S.C. § 112. In re Kamal, 398 F.2d 867, 870, 158 U.S.P.Q. 320, 322 (C.C.P.A. 1968). The language of the pending claims satisfies this requirement.

Contrary to the Examiner's assertion, the rejected terms have, in fact, been "clearly, concisely and exactly specified." Indeed, as noted above, each of these terms is very well-known in the chemical arts. See Hawley's Condensed Chemical Dictionary (attached). There can be no question that one skilled in the art understands the metes and bounds of these terms. Accordingly, withdrawal of the outstanding rejection under section 112, second paragraph, is requested.

In view of the foregoing, withdrawal of all objections and rejections and prompt allowance of this application are requested.

A petition for a three month extension of time and the requisite fee are being filed herewith. If there are any other fees due in connection with the filing of this paper, please charge the fees to Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested

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and the fee should also be charged to Deposit Account No. 06-0916.

Respectfully submitted,

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Date: December 13, 1994

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